IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
DAYTON DIVISION

DAYTON AREA CHAMBER OF COMMERCE; OHIO CHAMBER OF COMMERCE; MICHIGAN CHAMBER OF COMMERCE; and CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

Case No. 3:23-cv-00156-TMR-PBS

DECLARATION OF THOMAS QUAADMAN IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

DECLARATION OF THOMAS QUAADMAN

I, Thomas Quaadman, declare as follows:

1. I am Executive Vice President of the Global Innovation Policy Center at the Chamber of Commerce of the United States of America. In that capacity, I lead the efforts of the Global Innovation Policy Center to champion innovation and creativity through intellectual property standards that create jobs, save lives, advance global economic and cultural prosperity, and generate breakthrough solutions to global challenges.

2. The purpose of this declaration is to discuss the effects of the price control provisions of the Inflation Reduction Act on the Chamber's members and the irreparable harm that will result if the provisions are not enjoined.

3. Unless otherwise stated, this Declaration is based upon my personal knowledge and belief and/or upon my review of business records of the Chamber. If called as a witness, I could and would testify competently thereto.

I. The Chamber's Mission and Members

4. The Chamber is the world's largest business federation, representing approximately 300,000 direct members and indirectly representing more than three million U.S. businesses and professional organizations of every size and in every economic sector and geographic region of the country.

5. The Chamber has numerous members who will be directly subject to the IRA's price controls. Market analysts expect that multiple Chamber members will have drugs listed among the ten drugs selected by the Secretary for the IRA's price controls by September 1, 2023. Chamber members whose drugs are selected will be forced to enter "negotiations" with the Secretary, disclose competitively sensitive proprietary information to the Secretary, and "agree" to the Secretary's unreasonably low so-called "maximum fair price," which the Secretary can set without any statutory guarantee of a fair return on investment and without any administrative or judicial review. Because the statute sets a ceiling on such prices of at least 25 to 60% below market-price benchmarks, the price will be substantially lower than current market prices.

6. The Chamber's mission is to advocate for policies that help businesses grow and create jobs in their communities. As part of advancing that mission, the Chamber promotes effective private sector solutions to our health care challenges that will help control costs, expand access, and improve the quality of care. The Chamber also supports and defends the ability of private companies, including pharmaceutical manufacturers, to invest and innovate to improve health outcomes. Each stage of innovation requires enormous investment and risk-taking, and

that risk-taking is only made possible by the ability to recoup expenditures. The Chamber opposes artificial price controls that will hinder the ability of innovators to research, develop and bring to market new, innovative, and life-changing treatments for the benefit of all Americans. Instead, the Chamber advocates for a legal and political environment that will allow its members in the pharmaceutical and life sciences industry to do what they do best: develop the next generation of innovations that will improve patients' lives. Stable statutory and regulatory protections for manufacturers' property rights and investments, consistent with constitutional guarantees, are essential for the long-term decisionmaking that is required to develop new therapies and treatments.

II. The Impact of the Price Control Provisions of the IRA

7. As Executive Vice President of the Global Innovation Policy Center at the Chamber, I have worked closely with Chamber members and staff to understand how the price-control system would affect member businesses and the substantial and irreparable harm that will result from it.

8. The federal government is both regulator and dominant market participant in the healthcare field. Medicare, Medicaid, and other federal health programs account for nearly half of the nation's total healthcare expenditures, while the Department of Health and Human Services and the Centers for Medicare and Medicaid Services wield extensive authority over the federal health care programs. The Chamber's members participate in these markets and, as a practical matter, must do so. Even if the members were willing to cut themselves off from approximately half of the nation's market, the relevant statutory and regulatory provisions do not allow members currently participating in Medicare or Medicaid to exit these programs immediately.

9. The Inflation Reduction Act (IRA), passed in August 2022, requires HHS to establish what the statute calls a "Drug Price Negotiation Program," 42 U.S.C. § 1320f(a). Under that program, the Secretary must publish, by September 1, 2023, the ten Medicare Part D drugs selected for "negotiation." 42 U.S.C. § 1320f(d)(1). By October 1, 2023, manufacturers of selected drugs must sign "agreements" to "negotiate." *Id.* § 1320f(d)(2)(A). By October 2, 2023, manufacturers must submit extensive data requested by the Secretary. *Id.* § 1320f(d)(5)(A). By February 1, 2024, HHS will send to each manufacturer the government's initial "offer" of what it would establish as the "maximum fair price" for a specific drug. *Id.* § 1320f(d)(5)(B). By March 2, 2024, each manufacturer must either accept HHS's offer or send a "counteroffer." *Id.* § 1320f-3(b)(2)(C)(i). By August 1, 2024, HHS must decide the price that it is imposing. It then publishes the price as the "maximum fair price" by September 1, 2024, and the price goes into effect on January 1, 2026. *Id.* § 1320f(d)(5)-(6). The process will repeat annually, with additional drugs being selected each year. *Id.* § 1320f(b)(3). The prices imposed by HHS continue in effect until HHS determines that a generic or biosimilar version of the drug is approved or licensed and marketed pursuant to that approval or licensure. *Id.* § 1320f-1(c)(1).

10. The IRA contains no standard by which HHS should set the price, except that it should "achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f-3(b)(1). The statute does not set any threshold for what the "maximum fair price" must be; it simply defines the "maximum fair price" as whatever price the Secretary sets. Although permitting a manufacturer to "counteroffer" based on certain specified factors, the statute provides no standard for HHS to apply in considering such a counteroffer. HHS is free to reject the counteroffer and set whatever price it likes in its unreviewable discretion.

11. The IRA bars administrative and judicial review of the key determinations in this price-control scheme, including the selection of drugs and the determination of a maximum fair price. *Id.* § 1320f-7.

12. Numerous Chamber members will be subject to this price-control scheme, including by manufacturing drugs that market analysts expect to be on the first list, announced by September 1, 2023. They are facing critical decisions now about whether to launch new research and/or continue existing research into potentially life-changing medicines, recognizing that it costs billions of dollars to discover new drugs, conduct rigorous pre-clinical and clinical testing, and shepherd drugs through the lengthy FDA approval process. This new price-control scheme provides no guarantee that the manufacturers will even be able to recoup the costs of their investments, much less to ensure a fair return on those investments.

III. Enjoining the Price-Control Provisions of the IRA Would Remedy Harms to Members

13. Enjoining the price-control provisions of the IRA would remedy the above-referenced harms to the Chamber's members. It would enable them to avoid being exposed to confiscatory pricing and to continue to sell their products at market-based prices. It would also enable them to make investment decisions now to support innovation—investment decisions that would otherwise be put on hold, or decided adversely, because of uncertainty about their ability to recoup investment. And it would avoid the loss of customer goodwill that would accompany any effort to recoup losses later or that would accompany the government's declaration that a substantially below market price is the "maximum fair price" for the member's products.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 10th day of July at Washington, D.C.

Thomas Quaadman